



a member of the Roche Group

Ventana Medical Systems, Inc.  
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## Declaration of Conformity to 98/79/EC

Manufacturer: Ventana Medical Systems, Inc.  
1910 E. Innovation Park Drive  
Tucson, AZ USA 85755

European Authorized Representative: ROCHE DIAGNOSTICS GmbH  
Sandhofer Strasse 116  
D-68305 Mannheim  
Germany

Manufacturing Site: Tucson, AZ USA

|                                |  | Ventana  | Roche       |
|--------------------------------|--|--|-------------|
| Product name/<br>Catalogue No. | ultraView Universal DAB<br>Detection Kit | <span style="border: 1px solid black; padding: 2px;">REF</span><br>760-500 | 05269806001 |
| Technical Data File:           | TDF-0266                                 |  |             |
| Classification:                | General IVD                              |  |             |
| Conformity Assessment:         | 98/79/EC Annex III                       |  |             |

Ventana Medical Systems, Inc. declares that the product(s) listed is/are in conformity with the essential requirements of Annex I of Council Directive 98/79/EC. All supporting documentation is retained under the premise of the Manufacturer.

Ventana Medical Systems, Inc. maintains a quality system based on EN ISO 13485:2012 / EN ISO 13485:2012 + AC:2012 as certified by TÜV Rheinland LGA Products GmbH (Notified Body No. 0197).

Place of Issue: Tucson, AZ USA 85755

Name of Authorized Signatory: Troy Quander  
Vice President, Regulatory Affairs

Signature:

Date: 17 - March - 2015